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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,055	05/11/2006	Jun Mori	128006	1488

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EXAMINER	
LEWIS, AMY A	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
03/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,055	MORI ET AL.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Lack of Unity

Applicants allege that the lack of unity is improper because the special technical feature among the groups is the active agent 3-methyl-1-phenyl-2-pyrazolin-5-one. This is unpersuasive.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claims are directed to compositions and methods of making and treatments of 3-methyl-1-phenyl-2-pyrazolin-5-one. However, because Hiroyoshi et. al. (Japanese Application Publication No. 61-263917) teach the therapeutic use of this active agent, no special technical feature exists for groups I-III as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Note that PCT Rule 13 does not provide for multiple products or methods within a single application. Because the technical feature of Groups I-III is not a special technical feature, unity of invention is lacking.

Applicants elect Group III with traverse, in the response filed 8/19/08. In the original election requirement (mailed 7/28/08) the examiner stated that Group III (claims 6-15) is drawn to a method of treatment. Claims 6-10 as amended are now drawn to a method of manufacture. Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected subject matter, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiroyoshi et. al. (Japanese Application Publication No. 61-263917; provided by Applicant) in view of Koide et al. (Japanese Application Publication No. 10-265373).

Hiroyoshi et al. disclose the claimed active agent 3-methyl-1-phenyl-2-pyrazolin-5-one as a cerebral normalizing agent which has cerebral ischemia protecting action (abstract). The reference also teaches that the agent is "applicable to treatment of cephalic external wounds", thus teaching *external* application of the agent as a form of administration. While the '917 reference discloses a topical drug formulation comprising 3-methyl-1-phenyl-2-pyrazolin-5-one

in combination with well known excipients (abstract), it is silent with respect to the specific components of the percutaneous topical formulation.

The '373 patent discloses a tacky adhesive composition comprising a drug, water-soluble polymer, cross-linking agent a polyhydric alcohol and water (abstract). The water soluble polymers include rubber polymers such as polyacrylates [0013], and these polymers make up 1-15% [0014]. The formulation comprises crosslinking agents that make up from 0.1-10% of the formulation and include glycine [0017-0019]. The formulation comprises polyhydric alcohols such as ethylene glycol and propylene glycol that make up from 15-50% of the formulation [0020-0021]. The formulation further comprises tackifiers such as cellulosic resins, where the compounds are present in the formulation up to 15% [0020]. The water content of the formulation ranges from 40-70% [0038]. The drugs range from 0.001-10% of the drug formulation [0031] and can range from anti-inflammatory agents to muscle relaxants and vitamins [0030-0031]. The tacky formulation is applied to a film or substrate and applied to the skin [0022]. The tacky topical formulation, while disclosing a wide range of active agents is silent to the specific active agent of the instant claims.

The '917 reference discloses a topical drug formulation comprising 3-methyl-1-phenyl-2-pyrazolin-5-one in combination with well known excipients (abstract). It would have been obvious to combine the active agent of the '917 reference into the topical formulation of the '373 patent since they both teach topical formulations. Further, it would have been obvious to combine the compound of the '917 reference into the topical preparation of the '373 reference in order to improve the transdermal delivery of the active agent. One of ordinary skill in the art

would have been motivate to make this combination with an expected result of stable percutaneous formulation useful for external application as a means of administration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy A Lewis/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614